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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/772,105      | 01/26/2001  | Laurie J. Ozelius    | 0838.1001-009       | 7955             |

21005            7590            01/24/2002  
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[REDACTED]  
EXAMINER  
EINSMANN, JULIET CAROLINE

[REDACTED]  
ART UNIT            PAPER NUMBER

1655

DATE MAILED: 01/24/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |                     |
|------------------------------|------------------------|---------------------|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |
|                              | 09/772,105             | OZELIUS ET AL.      |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |
|                              | Juliet C Einsmann      | 1655                |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on \_\_\_\_ .

2a) This action is **FINAL**.                  2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-30 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_ is/are allowed.

6) Claim(s) \_\_\_\_ is/are rejected.

7) Claim(s) \_\_\_\_ is/are objected to.

8) Claim(s) 1-30 are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_ .
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

|   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                              | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)          | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ . | 6) <input type="checkbox"/> Other: ____ .                                   |

**DETAILED ACTION**

***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-13 and 28-30, all in part, drawn to nucleic acids that are fragments of the DYT1 gene (SEQ ID NO: 30-39, 48-56, and 88-90), classified in class 536, subclass 23.1.
  - II. Claims 1-13 and 28-30, all in part, drawn to nucleic acids that are fragments of the TORB gene (SEQ ID NO: 40-47 and SEQ ID NO: 57-63), classified in class 536, subclass 23.1.
  - III. Claims 14-23, drawn to methods for detecting polymorphisms, classified in class 435, subclass 6.
  - IV. Claims 24-27, drawn to methods for detecting the presence or absence of a dopamine-mediated disease in a mammal, classified in class 435, subclass 6.

**Further Restriction Requirement for Groups III and IV**

These groups recite the use of a number of different nucleic acid sequences. Each of these sequences correspond to separate sections of particular genes. For example, SEQ ID NO: 30-33 are all used for the amplification of exon 1 of the DYT1 gene. Restriction is required in these groups to a single exon of interest. If applicant elects group III or group IV, restriction is further required to an appropriate exon. Applicant should identify the gene and exon being elected as well as the appropriate sequences (by SEQ ID NO)

related to the elected exon. Failure to make such an election will result in the response being held non-responsive.

With regard to claim 15, a restriction requirement is further required between the four different genes listed. Applicant should elect a single gene for examination.

2. It is noted that every claim in this application is drawn to more than one invention. Prior to allowance, applicant will be required to cancel non-elected subject matter from any allowed claims.

3. It is further noted that claim 30 is written to depend from claim 29 which is a product claim, yet the preamble of claim 30 recites "The method of claim 29." For the purposes of the restriction requirement, claim 30 has been grouped with the products because of its dependency from claim 29. However, if applicant intends for the claim to be drawn to a method, further restriction may be necessary.

The inventions are distinct, each from the other because of the following reasons:

4. Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to nucleic acids that are fragments of genes that encode different proteins. Thus, the different nucleic acids have different structural sequences and have different functions.

5. Inventions of groups I and II are both related to the inventions of groups III and IV as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with

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another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acids of groups I and II can be used in separate methods, as is evidenced by their use in the two different methods of groups III and IV. In addition, the nucleic acids could be used in amplification methods for screening for the presence of the genes they are fragments of, in nucleic acid purification methods, and in expression methodology.

6. Inventions III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods with different goals requiring separate method steps, and the use of different reagents. The methods of group III are directed to the screening of nucleic acids for polymorphisms, while the methods of group IV are directed to the detection of the presence or absence of a disease.

7. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as demonstrated by their different classification and recognized divergent subject matter and because inventions I-IV require different searches that are not coextensive, examination of these claims would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

8. A telephone call was made to Doreen Hogle on 1/18/02 to request an oral election to the above restriction requirement, but did not result in an election being made.

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Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliet C. Einsmann whose telephone number is (703) 306-5824. The examiner can normally be reached on Monday through Friday, from 9:00 AM until 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 and (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Juliet C. Einsmann  
Examiner  
Art Unit 1655

January 22, 2002



W. Gary Jones  
Supervisory Patent Examiner  
Technology Center 1600